K070743

Section 5 -- 510(k) Summary

JUL - 2 2007

5.1 510(k) Owner

Name:	ST Cardio Technologies, LLC
Address:	3901 Troon Circle Broomfield, CO 80020
Phone:	303-324-9417
Fax:	303-648-5338
Contact Person:	William Abboud
Date:	March 13, 2007

5.2 Device Name

Trade Name:	Z6 Stimulator
Common Name:	Programmable Cardiac Electrophysiological Stimulator
Classification Name:	External Programmable Pacemaker Pulse Generator

5.3 Predicate Device

Company Name: Micropace Pty Ltd.
Device Name: EPS320 Clinical Stimulator

5.4 Device Description

The Z6 Stimulator is a cardiac pulse generator designed for use in an Electrophysiology Laboratory during electrophysiological studies. The system operates in conjunction with ECG Recording devices to deliver electrical stimulus to the patient's heart through up to four independent and simultaneously operable output channels. The Z6 Stimulator is controlled by a CPU based Workstation operating under Windows XP. This provides programmability and flexibility with regard to the stimulus protocols available to system users. Additionally, the system features a graphical interface with a Windows XP look and feel.

Each of the four independent output channels of the Z6 Stimulator is capable of generating between 0.1 and 25 mAs of current to the patient, with voltages up to 20 Volts. The system is capable of delivering pulses on all channels simultaneously. The duration of the pulses can be programmed to be between 0.5 and 10 ms, while maintaining timing accuracy (> +/- 0.15 ms).

5.5 Intended Use

The Z6 Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction

5.6 Technological Characteristics

Comparative Element	Micropace EP320 (Predicate Device)	Z6 Stimulator
510(k) Number	K011826	pending
Isolated Stimulus Channels	2	4
Pulse Amplitude	0.1-25 mA	0.1-25 mA
Pulse Duration	0.5-10 ms	0.5 to 10 ms
Interstimulus Interval	30-9900 ms	30-10000 ms
Number of Extra Stimuli	6	8
Display	15" LCD monitor	19" LCD monitor
Hardware Platform	Standard Personal Computer with custom Stimulus Generator Unit	Standard Personal Computer with Pulse Generation circuit board and custom Signal Conditioning Hardware.
Software Platform	Custom Application, Custom Real Time Operating System and Off the Shelf operating system Daylight ROM-DOS	Custom Application, Off the Shelf operating system Windows XP
User Interface	Graphical windowed display	Graphical windowed display
Preview Window	No	Yes
Catheter Tip IECG Sensing	Limited	No

5.7 Non-clinical Testing

Testing of the timing and amplitude accuracy of the Z6 Stimulator output pulses was compared to the specifications of the EP320 Stimulator output pulses. The Z6 Stimulator output pulses were found to be with in the specifications.

5.8 Non-clinical Testing Conclusions

The Z6 Stimulator output pulses were found to be with in the published specifications of the EPS320 Stimulator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2007

ST Cardio Technologies, LLC
c/o Mr. William J. Abboud
President and CEO
3901 Troon Circle
Broomfield, CO 80020

Re: K070743
Trade Name: Z6 Stimulator System
Regulation Number: 21 CFR 870.1750
Regulation Name: External Programmable Pacemaker Pulse Generator
Regulatory Class: Class II (two)
Product Code: JOQ
Dated: June 14, 2007
Received: June 15, 2007

Dear Mr. Abboud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 -- Indications for Use Statement

The Z6 Stimulator is intended for prescription use only.

Indications for Use:

The Z6 Stimulator System is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070743